# House File 434 - Introduced

HOUSE FILE 434
BY COMMITTEE ON HUMAN
RESOURCES

(SUCCESSOR TO HSB 121)

## A BILL FOR

- 1 An Act relating to the prescribing and dispensing of
- 2 self-administered hormonal contraceptives.
- 3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

- 1 Section 1. Section 155A.3, Code 2021, is amended by adding
- 2 the following new subsections:
- 3 NEW SUBSECTION. 10A. "Department" means the department of
- 4 public health.
- 5 NEW SUBSECTION. 44A. "Self-administered hormonal
- 6 contraceptive means a self-administered hormonal contraceptive
- 7 that is approved by the United States food and drug
- 8 administration to prevent pregnancy. "Self-administered
- 9 hormonal contraceptive" includes an oral hormonal contraceptive,
- 10 a hormonal vaginal ring, and a hormonal contraceptive patch,
- 11 but does not include any drug intended to induce an abortion as
- 12 defined in section 146.1.
- 13 NEW SUBSECTION. 44B. "Standing order" means a preauthorized
- 14 medication order with specific instructions from the medical
- 15 director of the department to dispense a medication under
- 16 clearly defined circumstances.
- 17 Sec. 2. NEW SECTION. 155A.47 Pharmacist dispensing of
- 18 self-administered hormonal contraceptives standing order —
- 19 requirements limitations of liability.
- 20 1. a. Notwithstanding any provision of law to the contrary,
- 21 a pharmacist may dispense a self-administered hormonal
- 22 contraceptive to a patient who is at least eighteen years of
- 23 age, pursuant to a standing order established by the medical
- 24 director of the department in accordance with this section.
- 25 b. In dispensing a self-administered hormonal contraceptive
- 26 to a patient under this section, a pharmacist shall comply with
- 27 all of the following:
- 28 (1) For an initial dispensing of a self-administered
- 29 hormonal contraceptive, the pharmacist may dispense only up
- 30 to a three-month supply at one time of the self-administered
- 31 hormonal contraceptive.
- 32 (2) For any subsequent dispensing of the same
- 33 self-administered hormonal contraceptive, the pharmacist
- 34 may dispense up to a twelve-month supply at one time of the
- 35 self-administered hormonal contraceptive.

pf/rh

- A pharmacist who dispenses a self-administered hormonal
- 2 contraceptive in accordance with this section shall not
- 3 require any other prescription drug order authorized by a
- 4 practitioner prior to dispensing the self-administered hormonal
- 5 contraceptive to a patient.
- 6 3. The medical director of the department may establish a
- 7 standing order authorizing the dispensing of self-administered
- 8 hormonal contraceptives by a pharmacist who does all of the
- 9 following:
- 10 a. Complies with the standing order established pursuant to
- ll this section.
- 12 b. Retains a record of each patient to whom a
- 13 self-administered hormonal contraceptive is dispensed under
- 14 this section and submits the record to the department.
- 15 4. The standing order shall require a pharmacist who
- 16 dispenses self-administered hormonal contraceptives under this
- 17 section to do all of the following:
- 18 a. Complete a standardized training program and continuing
- 19 education requirements approved by the board in consultation
- 20 with the board of medicine and the department that are related
- 21 to prescribing self-administered hormonal contraceptives and
- 22 include education regarding all contraceptive methods approved
- 23 by the United States food and drug administration.
- 24 b. Obtain a completed self-screening risk assessment,
- 25 approved by the department in collaboration with the board and
- 26 the board of medicine, from each patient, verify the identity
- 27 and age of each patient, and perform a blood pressure screening
- 28 on each patient prior to dispensing the self-administered
- 29 hormonal contraceptive to the patient.
- 30 c. Provide the patient with all of the following:
- 31 (1) Written information regarding all of the following:
- 32 (a) The importance of completing an appointment with the
- 33 patient's primary care or women's health care practitioner
- 34 to obtain preventative care, including but not limited to
- 35 recommended tests and screenings.

- 1 (b) The effectiveness and availability of long-acting
- 2 reversible contraceptives as an alternative to
- 3 self-administered hormonal contraceptives.
- 4 (2) A copy of the record of the pharmacist's encounter with
- 5 the patient that includes all of the following:
- 6 (a) The patient's completed self-screening risk assessment.
- 7 (b) A description of the contraceptive dispensed, or the
- 8 basis for not dispensing a contraceptive.
- 9 (3) Patient counseling regarding all of the following:
- 10 (a) The appropriate administration and storage of the
- 11 self-administered hormonal contraceptive.
- 12 (b) Potential side effects and risks of the
- 13 self-administered hormonal contraceptive.
- 14 (c) The need for backup contraception.
- 15 (d) When to seek emergency medical attention.
- 16 (e) The risk of contracting a sexually transmitted
- 17 infection or disease, and ways to reduce such a risk.
- 18 5. The standing order established pursuant to this section
- 19 shall prohibit a pharmacist who dispenses a self-administered
- 20 hormonal contraceptive under this section from doing any of the
- 21 following:
- 22 a. Requiring a patient to schedule an appointment with
- 23 the pharmacist for the prescribing or dispensing of a
- 24 self-administered hormonal contraceptive.
- 25 b. Dispensing self-administered hormonal contraceptives
- 26 to a patient for more than twenty-seven months after the
- 27 date a self-administered hormonal contraceptive is initially
- 28 dispensed to the patient, if the patient has not consulted with
- 29 a primary care or women's health care practitioner during the
- 30 preceding twenty-seven months, in which case the pharmacist
- 31 shall refer the patient to a primary care or women's health
- 32 care practitioner.
- 33 c. Dispensing a self-administered hormonal contraceptive to
- 34 a patient if the results of the self-screening risk assessment
- 35 completed by a patient pursuant to subsection 4, paragraph

- 1 "b", indicate it is unsafe for the pharmacist to dispense the
- 2 self-administered hormonal contraceptive to the patient, in
- 3 which case the pharmacist shall refer the patient to a primary
- 4 care or women's health care practitioner.
- 6. A pharmacist who dispenses a self-administered hormonal
- 6 contraceptive and the medical director of the department who
- 7 establishes a standing order in compliance with this section
- 8 shall be immune from criminal and civil liability arising
- 9 from any damages caused by the dispensing, administering,
- 10 or use of a self-administered hormonal contraceptive or the
- ll establishment of the standing order. The medical director of
- 12 the department shall be considered to be acting within the
- 13 scope of the medical director's office and employment for
- 14 purposes of chapter 669 in the establishment of a standing
- 15 order in compliance with this section.
- 16 7. The department, in collaboration with the board and
- 17 the board of medicine, and in consideration of the guidelines
- 18 established by the American congress of obstetricians and
- 19 gynecologists, shall adopt rules pursuant to chapter 17A to
- 20 administer this chapter.
- 21 Sec. 3. Section 514C.19, Code 2021, is amended to read as
- 22 follows:
- 23 514C.19 Prescription contraceptive coverage.
- 24 l. Notwithstanding the uniformity of treatment requirements
- 25 of section 514C.6, a group policy, or contract, or plan
- 26 providing for third-party payment or prepayment of health or
- 27 medical expenses shall not do either of the following comply
- 28 as follows:
- 29 a. Exclude Such policy, contract, or plan shall not
- 30 exclude or restrict benefits for prescription contraceptive
- 31 drugs or prescription contraceptive devices which prevent
- 32 conception and which are approved by the United States
- 33 food and drug administration, or generic equivalents
- 34 approved as substitutable by the United States food and
- 35 drug administration, if such policy, or contract, or plan

- 1 provides benefits for other outpatient prescription drugs
- 2 or devices. However, such policy, contract, or plan shall
- 3 specifically provide for payment of a self-administered
- 4 hormonal contraceptive, as prescribed by a practitioner as
- 5 defined in section 155A.3, or as prescribed by standing order
- 6 and dispensed by a pharmacist pursuant to section 155A.47,
- 7 including payment for up to an initial three-month supply
- 8 of a self-administered hormonal contraceptive dispensed at
- 9 one time and for up to a twelve-month supply of the same
- 10 self-administered hormonal contraceptive subsequently dispensed
- 11 at one time.
- 12 b. Exclude Such policy, contract, or plan shall not exclude
- 13 or restrict benefits for outpatient contraceptive services
- 14 which are provided for the purpose of preventing conception if
- 15 such policy, or contract, or plan provides benefits for other
- 16 outpatient services provided by a health care professional.
- 2. A person who provides a group policy, or contract, or
- 18 plan providing for third-party payment or prepayment of health
- 19 or medical expenses which is subject to subsection 1 shall not
- 20 do any of the following:
- 21 a. Deny to an individual eligibility, or continued
- 22 eligibility, to enroll in or to renew coverage under the terms
- 23 of the policy, or contract, or plan because of the individual's
- 24 use or potential use of such prescription contraceptive drugs
- 25 or devices, or use or potential use of outpatient contraceptive
- 26 services.
- 27 b. Provide a monetary payment or rebate to a covered
- 28 individual to encourage such individual to accept less than the
- 29 minimum benefits provided for under subsection 1.
- 30 c. Penalize or otherwise reduce or limit the reimbursement
- 31 of a health care professional because such professional
- 32 prescribes contraceptive drugs or devices, or provides
- 33 contraceptive services.
- 34 d. Provide incentives, monetary or otherwise, to a health
- 35 care professional to induce such professional to withhold

pf/rh

- 1 from a covered individual contraceptive drugs or devices, or 2 contraceptive services.
- This section shall not be construed to prevent a
   third-party payor from including deductibles, coinsurance, or
- 5 copayments under the policy, or contract, or plan as follows:
- 6 a. A deductible, coinsurance, or copayment for benefits
- 7 for prescription contraceptive drugs shall not be greater than
- 8 such deductible, coinsurance, or copayment for any outpatient
- 9 prescription drug for which coverage under the policy, or
- 10 contract, or plan is provided.
- ll b. A deductible, coinsurance, or copayment for benefits for
- 12 prescription contraceptive devices shall not be greater than
- 13 such deductible, coinsurance, or copayment for any outpatient
- 14 prescription device for which coverage under the policy, or
- 15 contract, or plan is provided.
- 16 c. A deductible, coinsurance, or copayment for benefits for
- 17 outpatient contraceptive services shall not be greater than
- 18 such deductible, coinsurance, or copayment for any outpatient
- 19 health care services for which coverage under the policy, or
- 20 contract, or plan is provided.
- 21 4. This section shall not be construed to require a
- 22 third-party payor under a policy, or contract, or plan
- 23 to provide benefits for experimental or investigational
- 24 contraceptive drugs or devices, or experimental or
- 25 investigational contraceptive services, except to the extent
- 26 that such policy, or contract, or plan provides coverage for
- 27 other experimental or investigational outpatient prescription
- 28 drugs or devices, or experimental or investigational outpatient
- 29 health care services.
- 30 5. This section shall not be construed to limit or otherwise
- 31 discourage the use of generic equivalent drugs approved by the
- 32 United States food and drug administration, whenever available
- 33 and appropriate. This section, when a brand name drug is
- 34 requested by a covered individual and a suitable generic
- 35 equivalent is available and appropriate, shall not be construed

-6-

- 1 to prohibit a third-party payor from requiring the covered
- 2 individual to pay a deductible, coinsurance, or copayment
- 3 consistent with subsection 3, in addition to the difference of
- 4 the cost of the brand name drug less the maximum covered amount
- 5 for a generic equivalent.
- 6 6. A person who provides an individual policy, or contract,
- 7 or plan providing for third-party payment or prepayment of
- 8 health or medical expenses shall make available a coverage
- 9 provision that satisfies the requirements in subsections
- 10 1 through 5 in the same manner as such requirements are
- 11 applicable to a group policy, or contract, or plan under those
- 12 subsections. The policy, or contract, or plan shall provide
- 13 that the individual policyholder may reject the coverage
- 14 provision at the option of the policyholder.
- 7. a. This section applies to the following classes of
- 16 third-party payment provider contracts, or policies, or plans
- 17 delivered, issued for delivery, continued, or renewed in this
- 18 state on or after July 1, 2000 January 1, 2022:
- 19 (1) Individual or group accident and sickness insurance
- 20 providing coverage on an expense-incurred basis.
- 21 (2) An individual or group hospital or medical service
- 22 contract issued pursuant to chapter 509, 514, or 514A.
- 23 (3) An individual or group health maintenance organization
- 24 contract regulated under chapter 514B.
- 25 (4) Any other entity engaged in the business of insurance,
- 26 risk transfer, or risk retention, which is subject to the
- 27 jurisdiction of the commissioner.
- 28 (5) A plan established pursuant to chapter 509A for public
- 29 employees.
- 30 b. This section shall not apply to accident-only,
- 31 specified disease, short-term hospital or medical, hospital
- 32 confinement indemnity, credit, dental, vision, Medicare
- 33 supplement, long-term care, basic hospital and medical-surgical
- 34 expense coverage as defined by the commissioner, disability
- 35 income insurance coverage, coverage issued as a supplement

- 1 to liability insurance, workers' compensation or similar
- 2 insurance, or automobile medical payment insurance.
- 3 8. This section shall not be construed to require a
- 4 third-party payor to provide payment to a practitioner for the
- 5 dispensing of a self-administered hormonal contraceptive to
- 6 replace a self-administered hormonal contraceptive that has
- 7 been dispensed to a covered person and that has been misplaced,
- 8 stolen, or destroyed. This section shall not be construed to
- 9 require a third-party payor to replace covered prescriptions
- 10 that are misplaced, stolen, or destroyed.
- 11 9. For the purposes of this section:
- 12 a. "Self-administered hormonal contraceptive" means a
- 13 self-administered hormonal contraceptive that is approved
- 14 by the United Sates food and drug administration to prevent
- 15 pregnancy. "Self-administered hormonal contraceptive" includes
- 16 an oral hormonal contraceptive, a hormonal vaginal ring, and
- 17 a hormonal contraceptive patch, but does not include any drug
- 18 intended to induce an abortion as defined in section 146.1.
- 19 b. "Standing order" means a preauthorized medication order
- 20 with specific instructions from the medical director of the
- 21 department of public health to dispense a medication under
- 22 clearly defined circumstances.
- 23 Sec. 4. INFORMATION PROGRAM FOR DRUG PRESCRIBING AND
- 24 DISPENSING SELF-ADMINISTERED HORMONAL CONTRACEPTIVES. The
- 25 board of pharmacy in collaboration with the board of
- 26 medicine and the department of public health shall expand
- 27 the information program for drug prescribing and dispensing
- 28 established pursuant to section 124.551, to collect from
- 29 pharmacists information relating to the dispensing of
- 30 self-administered hormonal contraceptives as provided pursuant
- 31 to section 155A.47. The board of pharmacy shall adopt
- 32 rules pursuant to chapter 17A related to registration of
- 33 participating pharmacists, the information to be reported by a
- 34 pharmacist to the information program, access to information
- 35 from the program, and other rules necessary to carry out the

pf/rh

```
1 purposes and to enforce the provisions of this section.
 2
                              EXPLANATION
           The inclusion of this explanation does not constitute agreement with
 3
            the explanation's substance by the members of the general assembly.
 5
      This bill relates to the dispensing of self-administered
 6 hormonal contraceptives by a pharmacist.
                                              The bill
 7 defines "self-administered hormonal contraceptive" as a
 8 self-administered hormonal contraceptive that is approved by
 9 the United States food and drug administration to prevent
10 pregnancy, including an oral hormonal contraceptive, a hormonal
11 vaginal ring, and a hormonal contraceptive patch, but not
12 including any drug intended to induce an abortion.
13
      The bill provides that notwithstanding any provision of law
14 to the contrary, a pharmacist may dispense a self-administered
15 hormonal contraceptive to a patient who is at least 18 years
16 of age pursuant to a standing order established by the medical
17 director of the department of public health (medical director).
18 For an initial dispensing, a pharmacist may dispense only up
19 to a three-month supply at one time of the self-administered
20 hormonal contraceptive, and for any subsequent dispensing
21 of the same self-administered hormonal contraceptive, a
22 twelve-month supply at one time. Additionally, the bill
23 prohibits a pharmacist who dispenses a self-administered
24 hormonal contraceptive in accordance with the bill from
25 requiring any other prescription drug order authorized by a
26 practitioner prior to dispensing the self-administered hormonal
27 contraceptive.
28
      The bill authorizes the medical director to establish a
29 standing order authorizing the dispensing of self-administered
30 hormonal contraceptives by any pharmacist who complies with the
31 standing order and retains and submits the patient's record to
32 the department of public health (DPH).
      The standing order includes requiring a pharmacist who
34 dispenses a self-administered hormonal contraceptive under
35 the bill to: complete a standardized training program and
```

1 continuing education requirements related to prescribing the 2 hormonal contraceptives; obtain a completed self-screening risk 3 assessment from each patient, verify the identity and age of 4 each patient, and perform a blood pressure screening on each 5 patient before dispensing the hormonal contraceptives; provide 6 the patient with certain written information; provide the 7 patient with a copy of the record of the pharmacist's encounter 8 with the patient; and provide patient counseling. The standing order would prohibit a pharmacist who dispenses 10 hormonal contraceptives under the bill from requiring a 11 patient to schedule an appointment with the pharmacist for 12 the prescribing or dispensing of the hormonal contraceptive; 13 dispensing the hormonal contraceptives to a patient for more 14 than 27 months after the date initially dispensed without the 15 patient's attestation that the patient has consulted with a 16 practitioner during the preceding 27 months; and dispensing 17 the hormonal contraceptives to a patient if the results of the 18 patient's self-screening risk assessment indicate it is unsafe 19 for the pharmacist to dispense the hormonal contraceptives 20 to the patient, in which case the pharmacist shall refer the 21 patient to a practitioner. The bill provides immunity for a pharmacist who dispenses a 22 23 self-administered hormonal contraceptive and for the medical 24 director who establishes a standing order in compliance with 25 the bill from criminal and civil liability arising from any 26 damages caused by the dispensing, administering, or use of a 27 self-administered hormonal contraceptive or the establishment 28 of the standing order. Additionally, the medical director 29 shall be considered to be acting within the scope of the 30 medical director's office and employment for purposes of Code 31 chapter 669 (Iowa tort claims Act) in the establishment of a 32 standing order in compliance with the bill. The bill requires DPH, in collaboration with the boards of 34 pharmacy and medicine, and in consideration of the guidelines

pf/rh

35 established by the American congress of obstetricians and

```
1 gynecologists, to adopt administrative rules to administer the 2 bill.
```

The bill amends prescription contraceptive coverage 4 provisions to require that a group policy, contract, or plan 5 delivered, issued for delivery, continued, or renewed in the 6 state on or after January 1, 2022, providing for third-party 7 payment or prepayment of health or medical expenses, shall 8 specifically provide for payment of self-administered hormonal 9 contraceptives, prescribed and dispensed as specified in 10 the bill, including those dispensed at one time. ll provides, however, that the provisions of the bill relating 12 to coverage are not to be construed to require a third-party 13 payor to provide payment to a practitioner for dispensing 14 a self-administered hormonal contraceptive to replace a 15 self-administered hormonal contraceptive that has been 16 dispensed to a covered person and that has been misplaced, 17 stolen, or destroyed. These provisions are also not to be 18 construed to require a third-party payor to replace covered 19 prescriptions that are misplaced, stolen, or destroyed. 20 The bill also requires the board of pharmacy in 21 collaboration with the board of medicine and DPH to expand 22 the information program for drug prescribing to collect 23 from pharmacists information relating to the dispensing of 24 self-administered hormonal contraceptives as provided in the

25 bill.